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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CARPENTER, WILLIAM R	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
08/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,041	FAGO, FRANK M.	
	Examiner	Art Unit	
	WILLIAM CARPENTER	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9-22,24,25 and 35-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7, 9-22, 24-25, and 35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 June 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-3, 15-20, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,554,792 ("Hughes") in view of US Patent No. 5,137,369 ("Hodan").

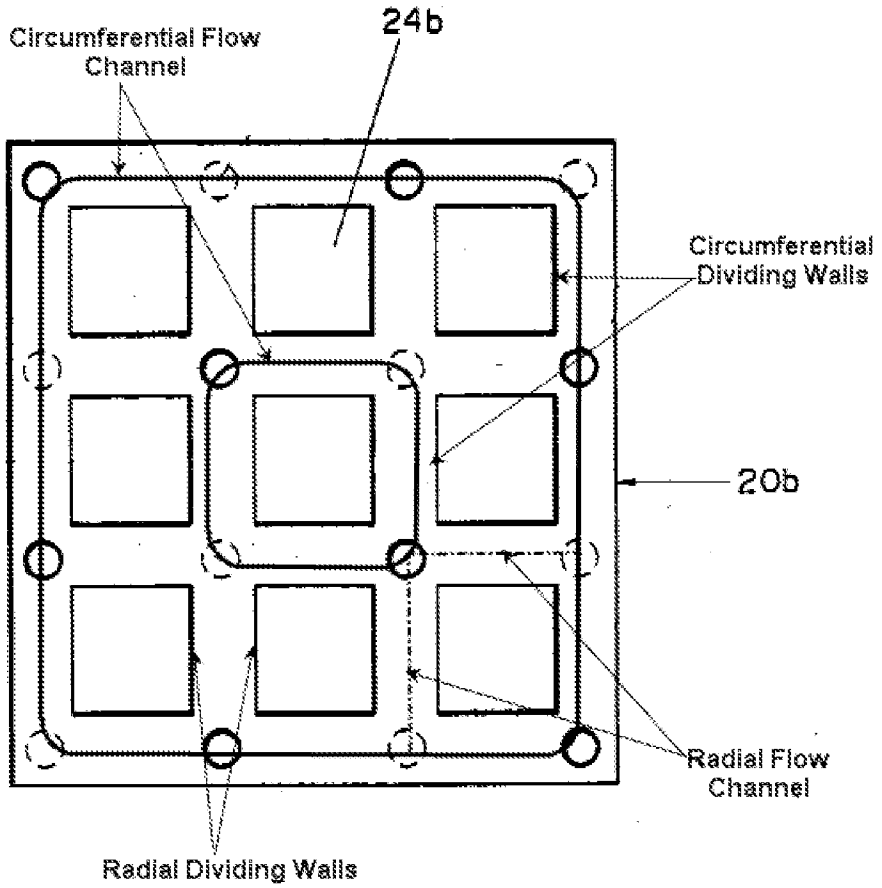
Regarding Claim 1-3, 15-20, and 41, Hughes discloses an apparatus/syringe (10) for administering a suspendible agent in suspension (Abstract). Hughes discloses the device to include a suspendible agent (12), in the form of contrast agent, suitable to be administered to a patient to diagnose or treat a medical condition (Abstract). Hughes discloses the device to comprise a deliver container/syringe barrel (14) including a fluid reservoir (36) holding a propellant fluid (16). Hughes discloses the delivery container to further comprise an exit port/first end (56), the device forming a fluid path between the fluid reservoir and the exit port (Fig. 1-5). Hughes discloses a delivery mechanism/plunger (58) slideably received in the second end, thereby defining the fluid reservoir, and operative for causing the propellant to flow through the fluid path (Abstract). Hughes discloses a variety of suspension apparatuses (8a, 8b, 8c, 8d, 8e, 8f, 8g, or 8h) disposed in the fluid path such that the suspendible agent is delivered to the exit port after flowing through the flow channels formed within the suspension apparatus when the delivery mechanism is operated to cause the propellant fluid to flow through the fluid path (Abstract). Hughes discloses that each of the suspension apparatuses defines a longitudinal axis (not shown) comprising a first longitudinal end and a second longitudinal end.

Hughes fails to disclose that the suspension apparatuses comprise a plurality of layers disposed between the first and second longitudinal ends, each of the plurality of

layers including a plurality of circumferential flow channels coupled by a plurality of radial flow channels, with each adjacent layer be fluidly coupled to the next by at least one axial flow channel. However, such suspension apparatuses are well-known in the art of static fluid mixing as exemplified by Hodan. Hodan discloses a suspension apparatus/static mixing device (Fig. 1) for delivering a suspendible agent in suspension comprising a suspension apparatus disposed within a fluid flow path (Fig. 1). Hodan discloses the suspension apparatus to define a longitudinal axis and to include a first longitudinal end (generally 12) and a second longitudinal end (generally 16), the first longitudinal end being in fluid communication with the second longitudinal end. Hodan discloses that between the first and second longitudinal ends are a plurality of layers (20a, 20b, and 20c), each of the layers including a plurality of circumferential flow channels (see attached figure) fluidly coupled to one another by a plurality of radial flow channels (see attached figure). Hodan discloses that each of the plurality of adjacent layers is fluidly coupled to one another by at least one axial flow channel (25). Hodan discloses that suspendible agent is delivered to the exit port (generally 17) after flowing through the plurality of radial flow channels and the plurality of circumferential flow channels mixing the fluid (Abstract). In the instant case the term “circumferential" is afforded its broadest reasonable interpretation as "the external boundary or surface of a figure or object" and “radial” is defined as “arranged as to gravitate towards or away from the center of a figure or object". As such the terms “radial” and "circumferential” do not necessitate that the body be circular. However, should Examiner’s arguments not be found persuasive, it would have been obvious for one having ordinary skill in the art at

the time the invention was made to form the apparatus of Hodan to be of a circular configuration as it has been held that a mere change in shape barring any showing of unexpected results requires only routine and customary skill. Hodan discloses the suspension apparatus to include a plurality of circumferential dividing walls (see attached figure) defining the plurality of circumferential flow channels. Hodan discloses that the suspension apparatus comprises a gap formed in a corresponding one of the plurality of circumferential dividing walls to define the radial flow channels (see attached figure). Hodan discloses that the circumferential dividing walls have a concentric arrangement (see attached figure). In the instant case, the phrase “concentric" is not held to exclusive necessitate a circular configuration, but may be broadly read as “having a common center”. However, as discussed above, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the layers of the device of Hodan to be circular in configuration, wherein the dividing walls will have a common center at the center of the circle. Hodan discloses that the suspension apparatus comprises a "pair" of first plates/layers (20a and 20c), the plurality of circumferential flow channels and the plurality of radial flow channels being distributed between said pair of first plates (Fig. 1). Hodan discloses the suspension apparatus to comprise a second plate (20b) positioned between the pair of first plates so as to separate the plurality of circumferential flow channels and said plurality of radial flow channels on an upstream surface of one of the pair of first plates from the plurality of circumferential flow channels and the plurality of radial flow channels on a downstream surface of the other of said pair of first plates (Fig. 1). Hodan discloses the

second plate to include an axial flow channel (25b) coupling the plurality of circumferential flow channels and the plurality of radial flow channels on one of the first plates with the plurality of circumferential flow channels and the plurality of radial flow channels on the other of the first plates (Fig. 1).



As both the device of Hughes and the device of Hodan are explicitly disclosed as being used for the purpose of static mixing within a fluid flow line and the both devices work on a similar mode of action (i.e. altering fluid flow path to mix said fluid; see especially Fig. 4 of Hughes), it would have been obvious for one having ordinary skill in the art at the time the invention was made to replace the suspension apparatus of the device of Hughes with a plurality of stacked plates, as disclosed by Hodan, thereby only

achieving the expected results of substituting one known inline static mixing device with a suitable alternative to obtain a predictable outcome. In the instant case the device of Hodan utilizes a circumferential barrier to form the outer edge of the plates. However, it would have been obvious for one having ordinary skill in the art at the time the invention was made to utilize the outer wall of the delivery container as the outer edge of the plates, as illustrated by Hughes (Figure 5), in order to reduce the quantity of material necessary to form the plates. Hughes demonstrates that disposing the suspension apparatus within the syringe body itself (Fig. 1, 4, and 5) is an obvious variant of an external compartment (Fig. 2 and 3).

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,554,792 ("Hughes") and US Patent No. 5,137,369 ("Hodan") as applied to Claim 2 above, and further in view of US Publication No. 2001/0056256 ("Hughes '01).

Regarding Claim 14, Hughes in view of Hodan discloses the invention substantially as claimed except that plurality of first dividing walls include irregularities that cause the suspendible agent flowing in the plurality of circumferential flow channels to change direction. However, Hughes '01 discloses a similar apparatus to that disclosed by Hughes. Hughes '01 discloses that irregularities in the flow network promote turbulence and induce interlaminar mixing to the contrast agent (Par. 70). As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to include irregularities in the dividing walls defining the flow channels of the modified device of Hughes,

as disclosed by Hughes '01, in order to cause a change in direction of the suspendible agent inducing increased beneficial mixing.

6. Claims 4, 5, 7, 9-13, 21-22, 24-25, and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,554,792 ("Hughes") in view of US Patent No. 5,137,369 ("Hodan"), and US Patent No. 4,869,849 ("Hirose").

Regarding Claims 4, 5, 7, 9-13, 21, 24-25, 35, 38, and 39, Hughes discloses an apparatus (10) for administering a suspendible agent in suspension (Abstract). Hughes discloses the device to comprise a delivery container/syringe barrel (14) including a side wall (36) extending between opposite ends of the delivery container. Hughes discloses the delivery container to have a fluid reservoir (generally 16) holding a propellant fluid (16) and at least partially bounded by the side wall, an exit port (24), a fluid path between the fluid reservoir and the exit port, and a delivery mechanism (58) operative for causing the propellant to flow through the fluid path. Hughes discloses the exit port to be sized and configured for delivery of the suspendible contrast agent (12) from the delivery container to a patient's body via a catheter connected to the luer lock connector (24).

Hughes further discloses the invention to comprise a suspension apparatus (46) defining at least a part of the fluid path and located within the deliver container adjacent to the reservoir such that the fluid path is at least partially bounded by the side wall of the delivery container (Figure 5). Hughes discloses the suspension apparatus to comprise a plurality of circumferential flow channels (12) capable of being filled with the suspendible agent and in fluid communication with the exit port.

Hughes discloses that the suspendible agent is delivered to the exit port after flowing through the plurality of circumferential flow channels when the delivery mechanism is operated to cause the propellant fluid to flow through the fluid path (Figure 5).

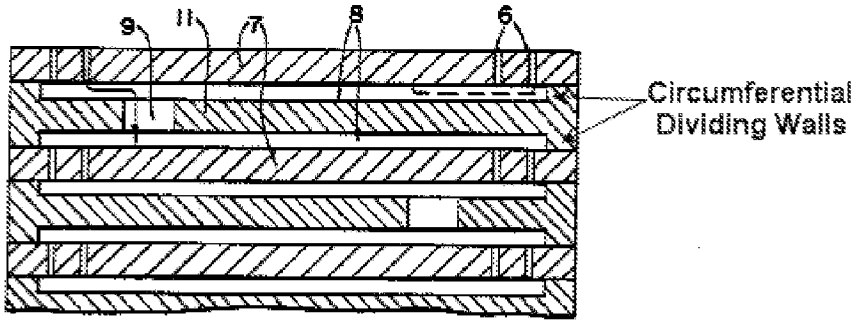
Hughes fails to disclose that the suspension apparatus comprises a plurality of plates having upstream and downstream surfaces wherein a plurality of circumferential dividing walls and radial flow channels are disposed. However, such suspension apparatuses are well-known in the art of static fluid mixing as exemplified by Hodan. Hodan discloses a static mixing device (Figure 1) for delivering a suspendible agent in suspension comprising a suspension apparatus comprising plurality of stacked plates (14, 20a, 20b, and 20c) disposed as part of a fluid flow path as to disrupt the flow of a fluid therethrough and mix said fluid (Abstract). Hodan discloses a plurality of first plates (20a, 20b, and 20c) carrying a plurality of circumferential dividing walls (24) defining a concentric plurality of circumferential flow channels (see attached figure) coupled in fluid communication by radial flow channels (see attached figure). In the instant case the term “circumferential" is afforded its broadest reasonable interpretation as "the external boundary or surface of a figure or object" and “radial” is defined as “arranged as to gravitate towards or away from the center of a figure or object". As such the terms “radial” and "circumferential” do not necessitate that the body be circular. However, should Examiner’s arguments not be found persuasive, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the apparatus of Hodan to be of a circular configuration as it has been held that a mere

change in shape barring any showing of unexpected results requires only routine and customary skill. Hodan discloses that the device is configured such that the suspendible agent would flow to the exit port through the radial and circumferential flow channels when the delivery mechanism is operated to cause the propellant fluid to flow through the fluid path. Hodan discloses that the first plate includes opposed upstream (visible in Figure 1) and downstream (side not visible) surfaces and an axial flow channel (25) extending between the upstream and downstream surfaces. Hodan discloses that the islands that form the circumferential dividing walls also contain sides that form radial dividing walls intersecting the circumferential dividing walls for blocking the flow channels and diverting fluid flow through the radial flow channels (see attached figure). Hodan discloses that axial flow channels may be located adjacent to a center of the first plate (25b) or adjacent a peripheral edge (25a) of the first plate.

As both the device of Hughes and the device of Hodan are explicitly disclosed as being used for the purpose of static mixing within a fluid flow line and the both devices work on a similar mode of action (i.e. altering fluid flow path to mix said fluid; see especially Figures 4 of Hughes), it would have been obvious for one having ordinary skill in the art at the time the invention was made to replace the suspension apparatus of the device of Hughes with a plurality of stacked plates, as disclosed by Hodan, thereby only achieving the expected results of substituting one known inline static mixing device with a suitable alternative to obtain a predictable outcome. In the instant case the device of Hodan utilizes a circumferential barrier to form the outer edge of the plates. However, it would have been obvious for one having ordinary skill in the art at

the time the invention was made to utilize the outer wall of the delivery container as the outer edge of the plates, as illustrated by Hughes (Figure 5), in order to reduce the quantity of material necessary to form the plates. Hughes demonstrates that disposing the suspension apparatus within the syringe body itself (Fig. 1, 4, and 5) is an obvious variant of an external compartment (Fig. 2 and 3).

Hughes, as modified by Hodan, fails to explicitly disclose if both the upstream and downstream surfaces comprise the plurality of the dividing walls, only explicitly illustrating the upstream surface to include said walls. However, Hirose discloses a similar inline static fluid mixing device (Figure 1) comprising a plurality of plates (11) disposed within a delivery container. Similarly to Hodan, Hirose discloses the plates to have dividing walls (not labeled) for separating the plates from one another and established fluid flow channels (8) therebetween with axial flow channels (9) interlinking the them. Differing from Hodan, Hirose discloses these dividing walls to be disposed on both the upstream and the downstream surfaces of the plates (Figure 4) with pairs of flat second plates (7) having axial flow channels (6) interlinking the pairs of first plates (Figure 4) in order to achieve a tight fluid seal.



It would have been obvious for one having ordinary skill in the art at the time the invention was made to modify the suspension apparatus of the modified device of Hughes to comprise a configuration of first plates having the dividing walls on opposed upstream and downstream surfaces and sandwiched between second flat plates, as disclosed by Hirose, thereby only achieving the expected results of substituting one well-known plate configuration in an inline static fluid mixer for another.

Regarding Claim 22, Hughes in view of Hodan and Hirose discloses the invention substantially as claimed except for explicitly disclosing that the ratio of volume of the flow channels to a volume occupied by the dividing walls is from approximately 0.25 to approximately 0.5. However, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the ratio of fluid flow channels to dividing walls of the modified device of Hughes to be within the range of 0.25 to 0.5, since it has been held that discovering the optimum or workable range of a result effective variable involves only routine skill in the art. The geometry of a fluid flow path is recognized as directly affecting the characteristic fluid flow therethrough.

Regarding Claim 36, Hughes discloses the device to comprise a delivery component (in the instant case a catheter, generally observable in Figure 2) connected to the luer lock (24) of the exit port to provide a delivery passageway between the delivery container and the patient's body such that the suspendible contrast agent is delivered from the exit port to the patient's body.

Regarding Claim 37, Hughes discloses the delivery container to comprise the barrel of a syringe, wherein the suspension apparatus is located within the barrel (Figure 5).

Regarding Claim 40, Hughes discloses that the propellant fluid may comprise a different composition, i.e. normal saline, water, buffer, or the like, as compared to the composition of the suspendible contrast agent.

Response to Arguments

7. Applicant's arguments filed with respect to the claims have been fully considered but they are not persuasive or are moot in view of the new ground(s) of rejection.

Applicant argues that “Hodan is directed to a static mixing device for homogenizing molten polymer. Thus, Hodan is non-analogous art. A person of ordinary skill would not look to Hodan's device, for mixing molten polymer, to administer a suspendible agent is suspension as claimed." This is not persuasive. Firstly, it is important to note that said “suspendible agent” is not even a positively required part of the workpiece as claimed, but rather a recitation of intended use of the device. As such, the device of Hodan need only be suitable for such a task. Secondly, said polymer may be reasonably considered a “suspendible agent” or even a suspension. Thirdly, the device of Hodan is specifically related to a static mixing device, an area that includes the requisite mixing required for various "suspendible agents". It is held that the disclosure of one mixing device would be directly applicable to another mixing device.

Applicant argues that "Hodan does not teach, suggest, or motivate a delivery mechanism for causing a propellant fluid to flow through the fluid path". This is not persuasive, Hodan inherently includes a delivery mechanism configured to cause the polymer through the fluid path, such a delivery mechanism is suitable for delivering an unclaimed "propellant fluid". Functional language drawn towards the intended use of the device merely necessitates that the prior art be capable of performing such a function, and no explicit teaching is required. Furthermore, the upstream quantity of the polymer itself may be considered a propellant fluid, since said fluid will inherently displace the downstream fluid, thereby acting as a propellant.

Applicant argues that "Hodan's inlet 11 is not a fluid reservoir; rather, it is a fluid inlet". However, Examiner submits that the two terms are not mutually exclusive from one another. As has been previously iterated the accepted definition of reservoir is "a part of an apparatus in which a liquid is held". The inlet of the device of Hodan holds a liquid, and is therefor a reservoir. Applicant appears to rely an unsupported narrowing of the definition of "reservoir" in an attempt to distinguish the claimed device over the prior art.

Applicant argues that "Hodan does not state the mechanism by which molten polymer enters the static mixer". However, it is inherently necessary that such a mechanism exists. Examiner may rely upon not only what is explicitly disclosed, but also what is inherent to a particular disclosure. Furthermore, based on the disclosure of Hodan, one skilled in the art would reasonably recognize and appreciate that the

inherent delivery mechanism must comprise a source of pressure in combination with gravity to propel said fluid through the mixing device.

Applicant argues that “Hodan does not teach, suggest, or motivate circumferential flow, let alone circumferential flow channels.” However, this is not found to be persuasive. As demonstrated in the attached figures, Hodan discloses at least two circumferential flow channels joined together by a plurality of radial flow channels. In the instant case the phrase “circumferential” is afforded its broadest reasonable interpretation as "of or pertaining to the external boundary or surface of a figure or object: PERIPHERY". Hodan clearly discloses the structure claimed by Applicant, and as such, the claims fail to define or distinguish over the prior art combination of Hughes and Hodan.

Applicant argues that “Hodan and Hirose are directed to mixing devices”. This fact is recognized by Examiner. Examiner also notes that Hughes is drawn towards a mixing device. Therefore, the teachings of Hodan and Hirose are applicable in the sense to modify to structure of the Hughes invention with alternative and/or beneficial structure.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is

(571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/
Examiner, Art Unit 3767
08/04/2009
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Supervisory Patent Examiner, Art Unit 3767